# COMMITTEE ON GOVERNMENT REFORM

**TOM DAVIS, CHAIRMAN**

# *MEDIA ADVISORY*

**For Immediate Release**
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## Dietary Supplements: Are They Safe? Do We Even Know?

*Davis Examines What Information, Protections are Available to Consumers*

What: **Government Reform Committee Hearing,**
**"The Regulation of Dietary Supplements:**
**A Review of Consumer Safeguards"**

When: **THURSDAY, March 9, 2006, 10:00 A.M.**
**(Hearing immediately follows Committee business meeting)**

Where: **ROOM 2154 Rayburn House Office Building,**

Background**:** The dietary supplement field is, by at least one estimate, a $20 billion industry. As many of 60 percent of all Americans take dietary supplements regularly, according to a government study conducted in 2004.

Supplements such as ephedra – banned in supplements by the Food and Drug Administration in 2004 after its use as a weight loss drug raised health concerns (and was cited in the death of Baltimore Orioles pitcher Steve Belcher) – have generated debate about the health and safety of supplements. Other supplements, still on the market, have been targeted by consumer groups as dangerous.

Yet there remains great – and potentially dangerous – confusion about how the dietary supplement industry is regulated. About 68 percent of adults, according to a 2002 Harris Poll survey, believe the federal government requires supplements to carry warning labels about potential side effects; 59 percent believe supplements must be approved by a government agency, like the Food and Drug Administration, before they can be sold; and 55 percent believe supplement manufacturers were not permitted to make claims regarding safety without solid scientific evidence.

Not one of those commonly-believed "facts" is true.

This hearing will examine what is the exact responsibility of the federal government in regulating dietary supplement and the role played by independent groups such as NSF International, U.S. Pharmacopeia, and Consumerlab.com. NSF, for example, helped create national packaging standards for supplements and now works with the NFL and Major League Baseball to certify that supplements do not contain banned substances such as performance-enhancing drugs.

The presence of performance-enhancing drugs in dietary supplements was illustrated by an October 18, 2005 article in the *Washington Post*. For the article, the newspaper purchased five dietary supplements, all labeled as muscle building supplements and all available over the Internet, and had them tested by the UCLA Olympic Analytical Laboratory for anabolic steroids. All five tested positive for what are commonly known as "designer steroids."

In addition to containing undisclosed and illegal performance-enhancing drugs, improper labeling is a violation under the 1994 Dietary Supplement Health and Education Act (DSHEA).

Under DSHEA, dietary supplement manufacturers do not need FDA approval before manufacturing, labeling, distributing, and marketing their products. FDA's regulation of dietary supplements is primarily a post-market program. For supplements that do not contain a new dietary ingredient – that is, a dietary ingredient that was not sold in the U.S. before October 15, 1994 – there is no requirement for manufacturers to provide FDA with evidence about the safety of the product either before or after marketing.

While DSHEA does require manufacturers to label their product as a "supplement" and include a full list of ingredients, manufacturers are not required to alert FDA to adverse event reports they may receive from consumers. Furthermore, DSHEA requires FDA to prove "a significant and unreasonable risk to health" before a dietary supplement can be removed from the shelves.

Ephedra was the first dietary supplement banned for sale by the FDA. But it continues to make news. Two weeks ago, the FDA announced that $3 million worth of products containing ephedrine alkaloids were seized from Hi-Tech Pharmaceuticals in Georgia. Hi-Tech manufactured three dietary supplements containing ephedrine alkaloids.

Finally, there are tools available to consumers to educate themselves on the private testing and verification of dietary supplements. Consumers have the ability to confirm a supplement's ingredients are properly detailed on the label, the percentage of each ingredient is accurate as labeled, and the supplement properly dissolves in the body. The hearing's second panel will discuss consumer education for athlete specific supplements, as well as commonly used vitamin and mineral supplements.

**Witnesses:**

Panel I

Dr. Robert E. Brackett, Director of the Center for Food Safety and Applied Nutrition, Food and Drug Administration

Dr. Paul M. Coates, Director of the Office of Dietary Supplements, National Institutes of Health

C. Lee Peeler, Deputy Director, Bureau of Consumer Protection, Federal Trade Commission

Panel II

Ms. Kathleen Jordan, General Manager, Dietary Supplements & Functional Foods Program, NSF International

Dr. V. Srini Srinivasan, Vice President, Verification Program, U.S. Pharmacopeia

Dr. Tod Cooperman, President and Founder, Consumerlab.com

Ms. Janell Mayo Duncan, Senior Counsel, Consumers Union

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